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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/613,903	07/11/2000	Heather J. Jordan	0942.4450001 (IVGN 187.1	1446

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INVITROGEN CORPORATION
C/O INTELLEVATE
P.O. BOX 52050
MINNEAPOLIS, MN 55402

EXAMINER

SISSON, BRADLEY L

ART UNIT	PAPER NUMBER
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1634

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/02/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

09/613,903

Applicant(s)

JORDAN, HEATHER J.

Examiner

Bradley L. Sisson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 November 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 65-127 and 129-139 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 65-127 129-139 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 22 November 2006 has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 65-127 and 129-139 are rejected under 35 U.S.C. 112, second paragraph, as failing to set forth the subject matter which applicant(s) regard as their invention.

4. Claim 65, and claims 55-84 and 130-134, which depend therefrom, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 65 is indefinite with respect to just what constitutes the metes and bounds of "substantially equal intensity." Claims 55-84 and 130-134, which depend from said claim 65, fail to overcome this issue and are similarly rejected.

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5. Claim 85, and claims 86-104 and 125-129, which depend therefrom, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 85 is indefinite with respect to just what constitutes the metes and bounds of the phrase "substantially equal relative mass." Claim 85 is also indefinite as a result of using the expression of nucleotides in place of a unit of mass. Consequently, it is not clear just what the mass of any one rung in the ladder is to have, much less how it is to vary from one rung to another of the ladder.

6. Claims 86-104 and 125-129, which depend from said claim 85 fail to overcome this issue and are similarly rejected.

7. Claim 105, and claims 106-125 and 130-137, which depend therefrom, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 105 is indefinite as to just what constitutes the metes and bounds of "substantially equivalent," and how this relates to both mass (even when as here no unit of mass is provided), as well as how it relates to copy number of fragments of nucleic acid that are to comprise each rung of a nucleic acid ladder, when the nucleic acid fragments may comprise labels and/or modified nucleotides.

8. Claims 106-124 and 130-139, which depend from claim 105, fail to overcome this issue and are similarly rejected.

9. Claim 101 recites the limitation "said detectable label" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.

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10. Claim 102 recites the limitation "said detectable label" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.

11. Claim 121 recites the limitation "said detectable label" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.

12. Claim 122 recites the limitation "said detectable label" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.

13. Claim 125 recites the limitation "the relative mass" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim. It is noted that claim 85, from which it depends, has support for "substantially equal relative mass," which has also been rejected under 35 USC 112, second paragraph, for being indefinite.

14. Claim 126 recites the limitation "the relative mass" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim. It is noted that claim 85, from which it depends, has support for "substantially equal relative mass," which has also been rejected under 35 USC 112, second paragraph, for being indefinite.

15. Claim 127 recites the limitation "the relative mass" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim. It is noted that claim 85, from which it depends, has support for "substantially equal relative mass," which has also been rejected under 35 USC 112, second paragraph, for being indefinite.

16. Claim 129 recites the limitation "the relative mass" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim. It is noted that claim 85, from which it depends, has support for "substantially equal relative mass," which has also been rejected under 35 USC 112, second paragraph, for being indefinite.

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17. Claim 129 is indefinite with respect to what constitutes "about the same."
18. Claim 134 is indefinite with respect to what constitutes the metes and bounds of "about the same intensity."

Claim Rejections - 35 USC § 102

19. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(f) he did not himself invent the subject matter sought to be patented.

20. Claims 65-82, 85-102, 105-122, 125-127 and 129-139 are rejected under 35

U.S.C. 102(b) as being anticipated by US Patent 5,316,908 (Carlson et al.).

21. Carlson et al., Fig. 1, disclose a nucleic acid ladder that meets the size, relative mass, and intensity requirements of claims 65-82, 85-102, 105-122, 125-127 and 129-139.

22. While claims 81, 82, 101, 102, 121, and 122 all recite detectable label to be used when performing the detection, however, the claims are not drawn to a method but to a product, which does not require the detectable label to be present.

23. Claims 65-82, 85-102, 105-122, 125-127 and 129-139 are rejected under 35

U.S.C. 102(f) because the applicant did not invent the claimed subject matter. It is noted that the assignee of the '908 patent and the instant application at the time of filing are one and the same, yet the inventorship is different.

Claim Rejections - 35 USC § 103

24. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

25. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

26. Claims 83, 84, 103, 104, 123, and 124 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5,316,908 (Carlson et al.) in view of US Patent 5,527,670 (Stanley).

27. See above for the basis of the rejection as it relates to the disclosure of Carlson et al.

28. Carlson et al., while teaching of the staining of a gel through the use of a dye, and of conducting gel electrophoresis, has not been found to disclose the addition of a dye such as bromophenol blue.

29. Stanley, column 10, second paragraph, discloses the addition of a loading dye, which comprises bromophenol blue, to a mixture of oligonucleotides that are to be separated via gel electrophoresis.

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30. It would have been obvious to one of ordinary skill in the art to have incorporated the use of a dye such as bromophenol blue, into the nucleic acid ladder composition of Carlson et al., as such would have facilitated the ready identification of the sample having been loaded into the gel and of its migration into the gel matrix. In view of the well-developed nature of gel electrophoresis, said artisan would have had a most reasonable expectation of success.

31. For the above reasons, and in the absence of convincing evidence to the contrary, claims 83, 84, 103, 104, 123, and 124 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5,316,908 (Carlson et al.) in view of US Patent 5,527,670 (Stanley).

Conclusion

32. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (571) 272-0751. The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

33. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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34. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Bradley L. Sisson
Primary Examiner
Art Unit 1634

BLS